Public Health **N**otifiable Conditions Determination 2005

Regulatory Impact Statement

Prepared as required under s34 of the *Legislation Act 2001*

Introduction

Section 34 of the *Legislation Act 2001* provides that the Minister must arrange for a regulatory impact statement (RIS) to be prepared for a subordinate law if it is likely to impose appreciable costs on the community, or part of the community. This RIS has been prepared to meet that requirement.

Section 35 of the *Legislation Act 2001* sets out the requirements for the content of a RIS prepared to meet the requirement under section 34. A copy of the content requirements is in Appendix 1. A brief assessment of the consistency of the Regulation with the scrutiny principles (required by s35(h)) is in Appendix 2.

Section 100 of the *Public Health Act 1997* (the Act) empowers the Minister to determine a disease or condition to be a notifiable condition. On 20 October 1999, a declaration under section 100 was gazetted. A copy of that determination is Appendix 3.

The Regulatory Environment

Part 6 of the Act establishes a scheme for various people to provide information about occurrences of certain medical conditions to the Chief Health Officer (the CHO), a statutory office established under the Act. In practice, the Communicable Disease Control (CDC) section of ACT Health accepts these notifications on behalf of the CHO. Sections 102, 102A, 103, 104 and 105 set out the obligations of doctors, nurses, pathologists, hospitals, counsellors and "persons responsible for the care, support and education" of a person.

The Policy Objectives of the Act and the Determination

The objectives of the Act are set out in section 4 of the Act. It reads as follows:

> This Act shall be construed and administered in accordance with the following objectives:
>
> (a) the protection of the public from public health risks including those associated with facilities, equipment, products and activities not adequately controlled by another law of the Territory or a law of the Commonwealth;
>
> (b) through the monitoring of health indicators, to provide the public with information about the health of the population and to design and implement appropriate policies and programs for the maintenance and improvement of the population's health;
>
> (c) the provision of a rapid response to public health risks;
>
> (d) the exercise of functions under this Act in a professional and responsible way;
>
> (e) the avoidance of any undue infringement of individual liberty and privacy in the exercise of functions under this Act.

The determination of notifiable conditions is part of the system that provides protection from public health risks, monitoring of health indicators and the provision of rapid response to public health risks. Section 99 of the Act sets out the principles and policy objectives of Part 6. The relevant part of that section provides that the provisions are to be used to "minimise the public health effects" of notifiable conditions.

This determination of notifiable conditions makes some changes to the list originally determined in 1999. The new determination adds:

- Avian Influenza
- Creutzfeldt-Jakob disease;
- Influenza;
- Severe Acute Respiratory Syndrome;
- Smallpox
- Tularemia; and
- Gastrointestinal illness cluster.

Lymphogranuloma Venereum and Chancroid have been removed from the list.

The various conditions listed in the determination have been chosen because

- there is a public health risk associated with the condition itself, or
- information about the incidence of the condition will assist in monitoring the effects of programs and polices intended to reduce the incidence of the condition (such as immunisation programs).

Some conditions are listed because of both of these factors.

Conditions in the list that represent a public health risk do so because

- there is a risk to others posed by the person having the condition, (because of the risk that the person with the condition either has already or may in future transmit the disease to others); or
- the existence of the condition is evidence that there is a food or vector borne disease present in the community.

Notification of this class of conditions allows intervention to

- educate and counsel the person about the risk that they potentially pose to others and how they can minimise that risk;
- find out from the person who they have exposed to the condition so that those people can be provided with appropriate information, advice and treatment;
- in the case of food and vector borne conditions, find out the source of the condition to that action can be taken to eliminate or reduce the risk that others will contract the condition.

The rationale for regulatory intervention for transmissible conditions is that people who have been exposed to a condition may not be aware that they have been exposed, and accordingly may not know that they need to seek treatment and take action to prevent exposing others. This issue is particularly acute in circumstances where there is a long lead time between infection and onset of symptoms. The intervention that is enabled by the notification process allows that lack of information to be addressed.

The rationale for regulatory intervention for food and vector borne conditions is that action can be taken to remove the threat of infection posed by the food source or the vector, or that those at can be informed of the risk and be enabled to take steps to minimise their risk of infection.

The rationale for intervention in relation to the balance of the conditions is to allow better data collection by Government to monitor programs for the reduction of the disease, which has the potential to allow more efficient allocation of resources to programs to reduce the incidence of these conditions.

Possible Alternative Regulatory Proposals

The only alternative to making a determination of notifiable conditions is to not make the determination. Since a determination was made in 1999, this option is the same as repealing that determination. Having repealed the determination, the Government could either do nothing to obtain notification of the diseases, or could conduct information campaigns to encourage reporting.

Accordingly, the options are maintain the status quo (with some changes of diseases), repeal the determination and do nothing, and repeal the determination and conduct information campaigns.

The following section compares the costs and benefits of these options.

Costs and Benefits

Option 1 – Maintain the status quo

Costs of Notification – private sector

CDC receives less than 2000 notifications per year under the 1999 declaration. It is expected that the number of notifications will rise to some degree under the new determination, possibly to as much as 2500 per year.

Notification is either provided in writing, or by a telephone call followed by written notification. CDC provides a notification form to reporters and requests that notifications are provided by facsimile.

The cost of notification are therefore (at most):

- the cost (in time spent and telephone charges) in making the phone call;
- the time in completing the form; and
- the cost of transmitting the form (by facsimile or by post).

The information required on the form is information the person collects from their patient/client in any event.

Notification comes from a range of professionals, some employed in Government, but the majority are employed in a private practice (in a medical or allied health role) or run their own practices. For those in the private sector, the cost of completing the paperwork and sending it in is the opportunity foregone to charge a patient or client

for services provided during that time, and the administrative cost of handling the report.

The time taken to make the call, fill in the form and post it will be about 10 minutes. The most expensive time is the doctor's time, so the cost will be over-estimated if it is assumed that all of this time is spent by a doctor. At time of writing, a short consultation fee in Canberra for a GP is typically $55. So if all the reports were made from the private sector, and all the work were done by GPs, and each notification amounted to forgoing the opportunity to do one short consultation, then the cost of 2500 reports per year would be $137,500 in foregone opportunities for income. (While this figure would be taxed, the taxable amount would go to public revenue, so the whole figure is a cost to the private and public sector).

The phone call and stationery costs would amount to a maximum of $2 per transaction, adding another $5,000 to the total.

Accordingly, an overestimate of the cost to the medical (and allied) professions of the reporting required under the determination is $142, 500.

Costs of Notification – public sector

The CDC is funded to provide the necessary administrative support to receive notifications and carry out follow up investigation and provision of information. For the purposes of this analysis, the cost of carrying out the investigation and follow up is separate (and would be carried out based on notifications received through any means, regardless of whether the notification was mandatory). It is therefore only necessary to consider the costs of receiving and storing the notification. These costs are:

- time spent receiving the phone call;
- time spent receiving, the written notification and filing it; and
- filing costs.

These times would also be less than 10 minutes each, and would amount therefore to less than 25,000 minutes each year, about 56 working days. The maximum pay (the top increment) for an ASO5 is $54,202 per annum. On costs (including superannuation, workers compensation and administration) amount to approximately 50% of this. The total cost is therefore approximately $81,257 per annum. 56 working days represents 21.5% of a working year, so the cost of receiving the notifications is approximately $17,500. Filing arrangements for notifications received mean that the costs for this are small. The total cost could be estimated at $17,500 per annum.

The total cost of the notification scheme to industry and government would therefore be $160,000 per annum. As noted above, this is a high estimate, to some degree.

Benefits of requiring notification

Receipt of notification of a notifiable condition has benefits that vary depending on the nature of the condition.

For conditions that can be transmitted person to person (the conditions marked as transmissible in the determination), notification allows counselling and education of

the person with the condition, and contact tracing. The education and counselling has the effect of reducing the likelihood that the person will infect others with the condition. The contact tracing allows those who have been potentially exposed to the condition to seek treatment (if they do not already know) and will also reduce the likelihood they will infect others with the disease.

In these cases, the public health intervention made possible by the notification reduces the spread of the condition in the community, and accordingly reduces the costs incurred in infected people seeking treatment (as fewer people will be infected and those infected will be able to seek treatment earlier). A reduced spread of the disease also has the intangible benefits of those who may have been exposed not getting sick in the first place.

These benefits are very difficult to quantify. However, as the conditions in question range from moderately serious to life threatening, the benefit of reducing their incidence in the community can be fairly said to be very large overall.

For vector and food borne diseases, notification allows the opportunity to trace the source of the vector or food contamination, which in some cases can allow action to prevent others being infected with the disease. This represents both the tangible benefit of reducing medical expenses of those potentially effected and the intangible benefits of better health overall for the community.

Where notification data is used to track the effectiveness of programs intended to reduce the incidence of disease (such as in the case of haemophilius influenzae type B), the benefit of the notification is the ability to more efficiently allocate the scarce resources available for such programs to get the maximum benefit from them. In particular, there is potential to determine whether a given program has had a measurable effect on reporting rates, and evaluate its effectiveness in light of that data. This efficiency benefit is difficult to quantify.

Reporting information is also used to target information and education campaigns in relation to particular condition. Where a condition is reported that a particular group is a high risk for (or where it is known that the circumstances of the report mean that a particular group is at risk) then information about reducing the risk of contracting the condition can be made available to that group. This has the effect of reducing the infection rate for the disease in that group, with obvious benefits of reducing the medical expenses and well being of that group.

Assessment of Net benefit of option one
While the benefits are difficult to quantify (and are to some degree intangible), it is clear that the benefit greatly exceeds the relatively modest costs associated with the reporting requirements.

The conclusion that there is a net benefit to the reporting requirement is not enough to select this option. The other options and the net benefit position in respect of them must be considered.

Option 2 – repeal the Determination and do nothing

This option would mean that there is nothing requiring the various reporters to provide information on incidence of these conditions. It can be expected that in the absence of a obligation to do so, the incidence of reporting of these conditions would be less. This would mean that the opportunity for managing the public health risk posed by the conditions would be reduced, and the information about the incidence of the diseases would be less useful (as it would represent less complete sample).

The costs identified in option 1 would be less, and over time would reduce to nothing as reporting rates dropped away. However, the significant benefits of reporting, particularly the reduced public health risk from communicable conditions would be lost.

Given that the benefits of requiring reporting significantly exceed the costs, it can be readily seen that reducing the costs and the benefits to nothing means that the net benefit of this option will be significantly less than option 1.

Option 3 – repeal the Determination and conduct information and education campaigns

This option would involve the Government in development of dissemination of information explaining the reasons why reporting of these conditions is desirable. This would involve more elaborate measures than are currently taken to promote the need now, as it would be necessary to persuade reluctant reporters to take action that involves some trouble and expense for them.

This education campaign would involve some additional resource investment for the Government, as statements that reporting is required by law would not be part of the information provided.

Even with an information campaign, incidence of reporting these conditions would be reduced. While costs of reporting would be reduced, so too would the benefits be reduced.

It is not proposed to analyse in detail the relationship between the level of reporting and the benefit gained. However, it can safely be assumed that with a reduced level of reporting, the level of benefit over time will be reduced.

The question to be considered here is whether this option would have a greater net benefit than option 1. In order for this to be true, the benefit would have to reduce by less the reduction in the cost. This will only be true where the difference in benefit of the two options was less than the difference in the costs of the two options.

The significant difference between the costs and benefits of option 1 means that this is very unlikely. It might occur when the most significant part of the benefit is derived from the set of reports that would be received even without a requirement to report. There is little evidence that this is the case. It is possible that some reports that are made only because they have to be will be reported that have a significant public benefit associated with them.

It cannot be safely concluded that the net benefit of option 3 will be greater than option1. Accordingly, option 1 should be considered to have a greater benefit than option 3.

Conclusions
Option 1 has been assessed as having the greatest, most certain public benefit, and is therefore preferred.

Appendix 1
Section 35 of the *Legislation Act 1991*

35 Content of regulatory impact statements

A regulatory impact statement for a proposed subordinate law or disallowable instrument (the ***proposed law***) must include the following information about the proposed law in clear and precise language:

(a) the authorising law;

(b) a brief statement of the policy objectives of the proposed law and the reasons for them;

(c) a brief statement of the way the policy objectives will be achieved by the proposed law and why this way of achieving them is reasonable and appropriate;

(d) a brief explanation of how the proposed law is consistent with the policy objectives of the authorising law;

(e) if the proposed law is inconsistent with the policy objectives of another territory law—

(i) a brief explanation of the relationship with the other law; and

(ii) a brief explanation for the inconsistency;

(f) if appropriate, a brief statement of any reasonable alternative way of achieving the policy objectives (including the option of not making a subordinate law or disallowable instrument) and why the alternative was rejected;

(g) a brief assessment of the benefits and costs of implementing the proposed law that—

(i) if practicable and appropriate, quantifies the benefits and costs; and

(ii) includes a comparison of the benefits and costs with the benefits and costs of any reasonable alternative way of achieving the policy objectives stated under paragraph (f);

(h) a brief assessment of the consistency of the proposed law with the scrutiny committee principles and, if it is inconsistent with the principles, the reasons for the inconsistency.

Appendix 2

The Scrutiny Principles

Section 35(h) of the *Legislation Act 2001* requires that this RIS contain a brief assessment of the consistency of the proposed law with the scrutiny committee principles and, if it is inconsistent with the principles, the reasons for the inconsistency.

As set out in the terms of reference of the Assembly's Standing Committee on Legal Affairs (when performing the duties of a scrutiny of bills and subordinate legislation committee). the relevant scrutiny principles are:

> (a) consider whether any instrument of a legislative nature made under an Act which is subject to disallowance and/or disapproval by the Assembly (including a regulation, rule or by-law):
>
> (i) is in accord with the general objects of the Act under which it is made;
>
> (ii) unduly trespasses on rights previously established by law;
>
> (iii) makes rights, liberties and/or obligations unduly dependent upon non-reviewable decisions; or
>
> (iv) contains matter which in the opinion of the Committee should properly be dealt with in an Act of the Legislative Assembly;

To briefly answer these (using the same numbering system):

(i) the Determination accords with the general objets of the Act;

(ii) the Determination does not trespass on rights previously established by law;

(iii) there are no non-reviewable decisions made under the Determination; and

(iv) the Act requires that this matter be dealt with by Determination, so it cannot sensibly be said to be a matter properly to be dealt with in an Act of the Legislative Assembly.